Attachment 6-2a

PROTOCOL CHECKLIST
FOR INITIAL SUBMISSION

These items are to be sent to NIH for final review and assignment of a protocol number:

Name of Investigator _____
Name of Study _____

☐ **Completed NIH-1195 (v. 9-06)**
☐ **Precis** (Please attach a one paragraph (<400 words) summary of the study objectives, study design, and outcome measures. Usually part of the protocol)

PROTOCOL WITH SECTION HEADINGS (OHSR Information Sheet #5)

☐ **BACKGROUND/INFORMATION**
☐ **OBJECTIVES**
☐ **STUDY DESIGN/METHODOLOGY**
☐ Study Design, including procedures and screening tests,
☐ Details of Experimental Treatment (where appropriate – for Clinical Studies)
☐ Toxicity Table (where appropriate – for Clinical Studies)
☐ **PARTICIPANT INCLUSION CRITERIA** (must be included)
☐ **PARTICIPANT EXCLUSION CRITERIA** (must be included)
☐ **PATIENT/SUBJECT MONITORING**
☐ **ADVERSE EVENTS**
Describe the plan for reporting of adverse events. Define what types of events constitute an adverse event.
☐ **STUDY ANALYSIS** (precise outcomes, statistical methods, power calculations)
☐ **HUMAN SUBJECT PROTECTIONS** (must be included)
☐ Subject selection criteria (including prevalence/population data/statistical considerations and strategies for recruitment, including advertising)
☐ Evaluation of Benefits and Risks/Discomforts
☐ Consent and Assent Procedures
☐ **REFERENCES INCLUDED**

OTHER ATTACHMENTS:

☐ **CLEARANCE OF NIH INVESTIGATOR PERSONAL FINANCIAL HOLDINGS BY IC ETHICS OFFICE (PFH)** Version 3/18/08 **(WITH DEC APPROVAL) (MANDATORY)**
☐ **DESIGNATION OF REIMBURSEMENT FOR TRAVEL AND SUBSISTENCE (DRTS) FORM (MANDATORY)**
☐ **CONSENT FORM (MANDATORY)(S)**
☐ **ADVERTISEMENT**
☐ **LETTERS TO SUBJECTS**
☐ **SCIENTIFIC REVIEW SUMMARY AND APPROVAL (MANDATORY)**
☐ **CORRESPONDENCE WITH PI**
☐ **C.V. FOR PI**
☐ **C.V. FOR ASSOC. INV.**
☐ **List of Off-Site Locations** if seeking approval off-site: Include their Federal Wide Assurance Number

OTHER REVIEWS REQUIRED? INCLUDE DOCUMENTATION

Radiation Safety	○ Yes	○ No
Biosafety	○ Yes	○ No
RAC	○ Yes	○ No
INVESTIGATIONAL NEW DRUG	○ Yes (Investigator's Brochure Submitted)	
	○ No	